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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,290	02/07/2001	Michael G. Wyllie	PC10325AAKM	8690

7590                    07/28/2003

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[REDACTED] EXAMINER

JONES, DWAYNE C

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1614  
DATE MAILED: 07/28/2003      10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/778,290	WYLLIE, MICHAEL G.
	Examiner Dwayne C Jones	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20MAR03.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-39 are pending.
2. Claims 1-39 are rejected.

### ***Response to Arguments***

3. Applicant's arguments filed March 20, 2003 have been fully considered but they are not persuasive with respect to the rejections under 103(a) in view of the prior art references of Hieble et al., Ukimura, as well as Hieble et al. in view of Ukimura. Applicant makes the following arguments. Applicant first argues that Hieble et al. teach of the activation of alpha-adrenoceptors in treating urinary incontinence and not the use of alpha-adrenoceptor antagonists. Applicant next argues that Ukimura do not teach of the combination of the alpha-adrenoceptor antagonists with muscarinic receptor antagonist.

4. Applicant makes the following arguments. Applicant first argues that Hieble et al. teach of the activation of alpha-adrenoceptors in treating urinary incontinence and not the use of alpha-adrenoceptor antagonists. This argument is only germane to claims 29-39, which are in fact directed to methods of treating lower urinary tract symptoms associated with benign hyperplasia. For this reason, Hieble et al. do teach of treating the lower urinary tract condition with an alpha-adrenoceptor antagonist, (see page 274s). In addition, Hieble et al. do teach of the administration of muscarinic antagonist also for treating lower urinary tract conditions, (see page 287s). Clearly the skilled

artisan would have been motivated to combine these pharmaceutical for the treatment of the very same condition of the lower urinary tract for composition claims 1-28. In addition, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

5. Next, applicant argues that Ukimura do not teach of the combination of the alpha-adrenoceptor antagonists with muscarinic receptor antagonist. Ukimura, however, does teach of the administration of alpha-adrenoceptor antagonists with muscarinic receptor antagonists for the treatment of lower urinary tract conditions. In addition, Ukimura teach of treating bladder contractility with the administration of these drugs on urodynamic parameters, (see abstract and page 252). Moreover, it is known in the art that one of the symptoms of benign hyperplasia causes an increased resistance to the urethral outflow of urine, (see Hieble et al. page 273s). In fact, Ukimura teaches that prazosin, an alpha-adrenoceptor antagonist, increases the bladder capacity and the muscarinic receptor antagonist, such as oxybutynin, also shows an increase in bladder capacity, (see page 258). Accordingly, the skilled artisan would have been motivated to combine these known pharmaceuticals to the same condition, which affects the lower urinary tract.

6. Furthermore, applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of

procedures and does not exclude materials or processes not recited in the claim".

*Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

***Claim Rejections - 35 USC § 112***

7. The rejection of claims 1, 11, 21 and 29 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the alpha-adrenoceptor antagonist of 4-amino-6,7-dimethoxy-2-(5-methanesulfonamido-1,2,3,4-tetrahydroisoquinol-2-yl)-5-(2-pyridyl)quinazoline, doxazosin, tetrazosin abanoquil, prazosin and indoramin and the muscarinic antagonist of darifenacin, tolterodine, oxybutynin, does not reasonably provide enablement for other types of alpha-adrenoceptor antagonists and muscarinic antagonists is withdrawn in response to the remarks of March 20, 2003.

***Claim Rejections - 35 USC § 102***

8. The rejection of claims 1-28 under 35 U.S.C. 102(b) as being clearly anticipated by Hieble et al. is removed in response to the remarks of March 20, 2003.

9. The rejection of claims 1-28 under 35 U.S.C. 102(b) as being clearly anticipated by Ukimura is withdrawn in response to the remarks of March 20, 2003 but it converted into a rejection under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1614

11. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ukimura. Ukimura, however, does teach of the administration of alpha-adrenoceptor antagonists with muscarinic receptor antagonists for the treatment of lower urinary tract conditions. In addition, Ukimura teach of treating bladder contractility with the administration of these drugs on urodynamic parameters, (see abstract and page 252). Moreover, it is known in the art that one of the symptoms of benign hyperplasia causes an increased resistance to the urethral outflow of urine, (see Hieble et al. page 273s). "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The skilled artisan would have been motivated to combine these pharmaceuticals for the treating the same condition of the lower urinary tract in view of *In re Kerkhoven*.

12. The rejection of composition claims 1-28 under 35 U.S.C. 103(a) as being unpatentable over Hieble et al. is maintained for both the above-stated and reasons of record.

13. The rejection of composition claims 1-39 under 35 U.S.C. 103(a) as being unpatentable over Hieble et al. in view of Ukimura is maintained for both the above-stated and reasons of record.

***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

Dwayne C. Jones  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
July 24, 2003